COUNTERFEIT DRUGS – THE LATEST HEALTH SCARE?

The menace of counterfeit drugs is no longer a possibility; it is with us now and growing at a phenomenal rate, according to organisations such as the World Health Organisation (WHO) and The Association of British Pharmaceutical Industry (ABPI). WHO, for example, estimates that "on average 10% of the world's drug supply is considered counterfeit, adulterated or otherwise fraudulent, although in some developing countries it could be as high as 33%." [1] Instrumentation using Energy Dispersive X-ray Diffraction technology is discussed as one approach to testing drugs for alteration or substitution.

While many internet users are familiar with email messages extolling the virtues of lifestyle drugs targeting areas such as 'weight loss' and 'erectile dysfunction' it may not be so apparent that purchasing drugs in this way offers potential dangers.

Products available from internet pharmacy sites which conceal their address, for example, are estimated by the World Health Organisation to be 50% counterfeit.

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relatively lower for the US and European countries, where strict regulations act as a barrier to such measures, the impact on developing countries is far more devastating. Taking the UK as an example, in the past three years there have been nine recalls of specific batches of counterfeit medicines all of which had reached the pharmacy and patient level. There have also been a number of reports of counterfeit medicinal devices discovered inside UK borders or seized on their way to the UK [3].

The Association of the British Pharmaceutical Industry (ABPI), has estimated "that the process (Counterfeit Drugs) in 2005 cost the industry 1.46 billion Euros" [3] while in 2006 customs officials reported "a fivefold increase, in one year, in counterfeit medicine discoveries - 2.7million drugs in 500 seizures." [4]

The problem is highlighted by one particularly devastating case, that of 26-year-old Selena Walrond, from Croydon in South London who was just looking for a slimmer version of herself. From a Chinese website she purchased DNP, dinitrophenol, a fat burning chemical which boasts an increase of 50% in metabolic rate which can result in a 10 - 12 pound weight loss in just 8 days. The following day, Selena was found with a racing pulse and feverish. She was rushed to the hospital by her mother and died of cardiac arrest.

DNP is as dangerous as it is effective – making it one of the first drugs to be banned in the US by The Food and Drug Administration (FDA) back in 1938 and it has never been approved in the UK. The drugs side effects include sweats, insomnia, cataracts, and death. [5]

Spectroscopy Focus

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WHAT IS A COUNTERFEIT DRUG? THERE ARE FOUR BASIC CATEGORIES OF COUNTERFEITS:

1 - Completely fraudulent medications with no active ingredients or clinical benefit.

In some cases the ingredients may actually be toxic or pose a significant risk to the person taking the medication. It is estimated that 40% of the counterfeit drugs currently in circulation do not even contain an active ingredient from the original medicine.

2 - Counterfeit medicines, which contain poor quality ingredients or a diluted affect ingredient

These medicines pose a significant health risk because even though there may be some clinically beneficial ingredients in the counterfeit, their medicinal value is unknown or extremely limited. Use of these counterfeits will cause harm to the person or at best give only a partial respite against their ailment.

3 - Expired medications, which have been repackaged and sold as new.

These also are a significant health risk because the active constituent may have degraded to be at least ineffective or at worst dangerous to the patient.

4 - Medications that mimic the pharmaceutical formula using unknown raw materials/ ingredients and manufacturing processes

The patient benefit of these counterfeits is completely unknown and should be considered extremely hazardous given the lack of testing, regulation and quality control. These counterfeits are primarily produced to infringe on a pharmaceutical manufacturers patent and again the quality and efficacy of the medication is completely unknown.

The reported incidence of drug tampering from different regions (*see Table 1)*, shows that the practice is established worldwide; while reported levels remain

In many other countries the situation is much worse where products available through the normal supply chain have also been targeted. Dr Dora Akunyilli, Head of Nigeria's Drug Control Agency said "84% of Nigeria's Malaria drugs are counterfeit. Artemisin is the last remaining effective anti-malarial and when this is faked, any hopes the world once had of beating this disease can be forgotten".

Just to put this into perspective, *Table 1* shows statistics from the World Health Organization on the Prevalence of Counterfeit Drugs in the West and the Developing World. These statistics represent WHO's 2006 estimates as to the percentage of counterfeit or adulterated drugs within that country or regions total drug supply chain.

Table 1

United States	less than 1%
United Kingdom	less than 1%
Europe	less than 1%, (Est 10%)
Nigeria	16%
Kenya	30%
Lebanon	35%
Cambodia	13%
China	8% on OTC medications
India	10-20%
Indonesia	25%
Russia	10%
Former Soviet Republics	20%
Colombia	5%
Mexico	10%
Peru	15-20%
Venezuela	25%

These numbers were all presumed to be very low at the time and many of the percentages may have nearly doubled since 2006.

Some of the latest countermeasures, designed to prevent drug counterfeits, are also facing problems tackling drug adulteration issues; RFID (Radio Frequency Identification) labels for example, will not "be able to overcome some of its technical and economic hurdles and be able to meet regulatory deadlines scheduled to take effect in the near future" and "have already been counterfeited," according to WHO [6].

Until recently, EDXRD analysis was carried out primarily by leading universities for material testing usually involving the use of massive synchrotron facilities often larger than a football field. Then in the early nineties, a professor at Rutgers University in New Jersey, USA was awarded a grant to develop an EDXRD system, which could be used to scan large baggage items for explosive materials [7]. Recent developments in EDXRD technology have now brought a new bench size approach to the battle against counterfeit drugs.

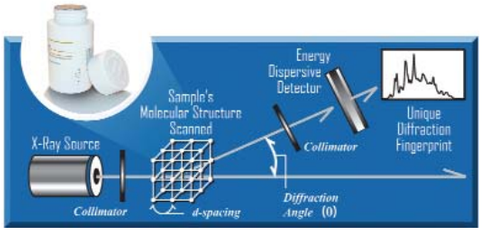
The resulting XStream XT250™ EDXRD benchtop system (below) works on the same principals, as it's enormous predecessors by diffracting x-rays off the atoms within a sample *(see Table 2)*

Table 2

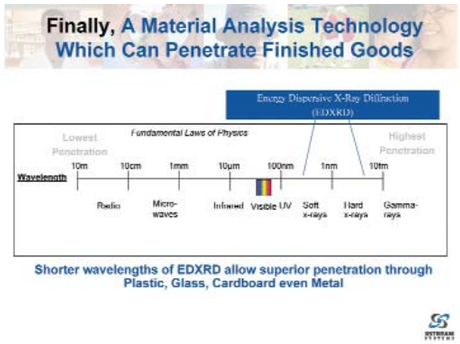
The XStream XT250 ™ System's results are the outcome of five steps:

1. A high intensity beam of x-rays are generated by an x-ray source safely concealed in the heart of the instrument.
2. A primary collimator is used to control and focus the beam.
3. The beam is directed through the sample container.
4. The crystals of the sample diffract the beam and a second collimator allows a key portion of the altered beam to hit an energy dispersive detector.
5. A Material Recognition Software Engine (MRSE) is used to compare the unique fingerprint with the library in the database.

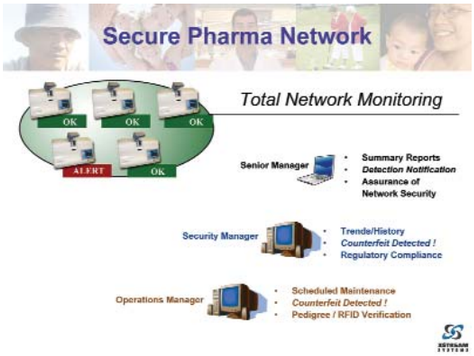
Independent tests have shown that the XStream XT250 ™ EDXRD system has an accuracy of 99.4% when identifying pharmaceuticals such as Tagamet HB 200, Aleve, Dramamine, Motrin IB, Nuprin, Zantac 150 and BC powder. [8]



EDXRD systems differ from common x-ray units in that they collect diffracted information and discard the normal imaging data. A cadmium telluride detector within the unit then transmits its findings to a computer, which runs the results through a set of algorithms to provide the a pass/fail result. The X-ray source of an EDXRD system penetrates the surface layer of a sample to test and identify material beneath without touching it in any way; this makes it very difficult to fool or inadvertently contaminate the system – a true advantage over authentication equipment, which offer surface analysis only, or which require destructive testing.



This also means that EDXRD methodology has the ability to validate or authenticate materials while still in original sealed containers. In pharmaceutical applications, a bottle of pills can be checked in their manufacturer's opaque, sealed packaging; and when found to be legitimate can continue on their path through the supply network. In a similar vein, if a contrary result is found then the sealed container maintains the evidential security.



Xstream EDXRD systems may be networked within an individual company site or within an entire production to distribution to retail chain, each analysis contributing to the database and providing greater and greater security of identification.

They are suitable for use in a wide range of industries including the pharmaceutical industry, food manufacture, drug enforcement agencies, forensic laboratories, chemical manufacture, mining, cosmetics, veterinary forensic laboratories, and herbal medicines.

REPORTING COUNTERFEIT MEDICINE AND DEVICES

The MHRA (UK) has launched a 24 hour hotline to allow the public, healthcare professionals, those engaged in the supply chain and industry to report any suspicions they have about a product directly and where necessary confidentially, to the MHRA, by telephone: 0207 0842701 or through the MHRA website www.mhra.gov.uk

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